

DETAILED ACTION

Claims 1-39 are pending.

Election/Restrictions

1. Applicant's election without traverse of claims 22-28 and *Bifidobacterium* sp. 420 in the reply filed on August 15, 2009 is acknowledged.
2. Claims 1-21 and 29-39 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. The species election is deemed proper and is therefore made FINAL.
3. Claims 22-28, insofar as they read upon the elected species, are examined on the merits in this office action.

Specification

4. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. Appropriate correction is required. For instance, applicant may amend the title of the invention to "A Method of Increasing the Amount of COX-1 mRNA in a Subject" or some other appropriate title.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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6. Claim 28 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim is rendered indefinite by the recitation of "a betaine replacement compound." It is unclear what compounds would be suitable for replacement of betaine in the instant invention and, therefore, what compounds would meet the claim limitations. For instance, applicant could intend for the claim to recite a compound with the same osmotic effects as betaine or one with similar chemical characteristics to betaine. Therefore, the metes and bounds of the claims would be unclear to one of ordinary skill in the art.

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claim 27 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

9. The invention appears to employ a specific strain of bacteria, i.e. *Bifidobacterium* sp. 420. It is not clear if the written description is sufficiently repeatable to avoid the need for a deposit. Further it is unclear if the starting materials were readily available to the public at the time of invention.

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10. It appears that the species is available commercially at the time the application was filed, as noted on page 22 of the specification. However, it is not clear whether a deposit has been made and if the deposit meets all of the criteria set forth in 37 CFR 1.801-1.809. Applicant or applicant's representative may provide assurance of compliance with the requirements of 35 U.S.C § 112, first paragraph, in the following manner.

SUGGESTION FOR DEPOSIT OF BIOLOGICAL MATERIAL

A declaration by applicant, assignee, or applicant's agent identifying a deposit of biological material and averring the following may be sufficient to overcome an objection and rejection based on a lack of availability of biological material.

1. Identifies declarant.
2. States that a deposit of the material has been made in a depository affording permanence of the deposit and ready accessibility thereto by the public if a patent is granted. The depository is to be identified by name and address.
3. States that the deposited material has been accorded a specific (recited) accession number.
4. States that all restriction on the availability to the public of the material so deposited will be irrevocably removed upon the granting of a patent.
5. States that the material has been deposited under conditions that access to the material will be available during the pendency of the patent application to one determined by the Commissioner to be entitled thereto under 37 CFR 1.14 and 35 U.S.C § 122.
6. States that the deposited material will be maintained with all the care necessary to keep it viable and uncontaminated for a period of at least five years after the most recent request for the furnishing of a sample of the deposited microorganism, and in any case, for a period of at least thirty (30) years after the date of deposit for the enforceable life of the patent, whichever period is longer.
7. That he/she declares further that all statements made therein of his/her own knowledge are true and that all statements made on information and belief are believed to be true, and further that these statements were made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the instant patent application or any patent issuing thereon.

Alternatively, it may be averred that deposited material has been accepted for deposit under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the purpose of Patent Procedure (e.g. see 961 OG 21, 1977) and that all restrictions on the availability to the public of the material so deposited will be irrevocably removed upon the granting of a patent.

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Additionally, the deposit must be referred to in the body of the specification and be identified by deposit (accession) number, date of deposit, name and address of the depository and the complete taxonomic description.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 22-26 and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Collins (US 2002/0006432 A1). Claim 22 recites a method of treating and/or preventing the side-effects associated with the administration of nonsteroidal anti-inflammatory drugs, which method comprises administering to the patient an effective amount of a microorganism and/or a metabolite thereof, which microorganism and/or metabolite thereof at least increases the amount of a COX-1 mRNA in at least one cell of the subject. Claims 23 and 24 recite the method according to claim 22, wherein the microorganism and/or the metabolite thereof modifies the amount of a thither cyclooxygenase mRNA in said cell and wherein the microorganism and/or the metabolite thereof increases the amount of a COX-1 mRNA in said cell, whilst simultaneously decreases the amount of a COX-2 mRNA in said cell. Claims 25-27 recite the method according to claim 22, wherein the microorganism is a bacterium, specifically from the genus *Bifidobacterium*. Claim 28 recites method according to claim

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22, wherein the subject is further administered with an effective amount of betaine or a pharmaceutically acceptable salt thereof or a betaine replacement compound.

13. Collins teaches a method of treating a subject by administering bacteria of the genus *Bifidobacterium* to a subject (abstract). The reference teaches that the bacteria may be administered in conjunction with NSAIDs (p. 4, par. 76). The functions recited in the claims, i.e., the effect on mRNA, would be inherent to the method of Collins.

14. Therefore, the reference anticipates all of the limitations of the cited claims.

Claim Rejections - 35 USC § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

16. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

17. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

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were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

18. Claims 22-26 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Collins (US 2002/0006432 A1) in view of Zimmer (US 5,501,857) or Chen et al. (US 2001/0014322 A1). Claim 22 recites a method of treating and/or preventing the side-effects associated with the administration of nonsteroidal anti-inflammatory drugs, which method comprises administering to the patient an effective amount of a microorganism and/or a metabolite thereof, which microorganism and/or metabolite thereof at least increases the amount of a COX-1 mRNA in at least one cell of the subject. Claims 23 and 24 recite the method according to claim 22, wherein the microorganism and/or the metabolite thereof modifies the amount of a thither cyclooxygenase mRNA in said cell and wherein the microorganism and/or the metabolite thereof increases the amount of a COX-1 mRNA in said cell, whilst simultaneously decreases the amount of a COX-2 mRNA in said cell. Claims 25-27 recite the method according to claim 22, wherein the microorganism is a bacterium, specifically from the genus *Bifidobacterium*. Claim 28 recites method according to claim 22, wherein the subject is further administered with an effective amount of betaine or a pharmaceutically acceptable salt thereof or a betaine replacement compound.

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19. Collins teaches a method of treating a subject by administering bacteria of the genus *Bifidobacterium* to a subject (abstract). The reference teaches that the bacteria may be administered in conjunction with NSAIDs (p. 4, par. 76). The functions recited in the claims, i.e., the effect on mRNA, would be inherent to the method of Collins. The reference does not specifically teach the addition of a betaine or betaine replacement compound to the composition comprising the bacteria.

20. Zimmer and Chen teach compositions comprising probiotic bacteria, such as a *Bifidobacterium*, and choline (a betaine replacement compound; see Zimmer, abstract, col. 12, example 1; and Chen, abstract, p. 3, par. 21).

21. At the time of the invention, a method of administering the bacterium recited in the claims was known, as taught by Collins. It was further known that such bacteria could have been administered with a betaine replacement compound, as taught by Zimmer and Chen. One of ordinary skill in the art would have been motivated to combine the teachings by administering the betaine replacement compound in the method of Collins because both Zimmer and Chen teach that it is desirable to administer bacteria in combination with such components. One of ordinary skill in the art would have had a reasonable expectation of success in combining the components in a method such as that recited in the claims because Zimmer and Chen both teach that betaine replacement compounds are compatible with the bacteria. It would therefore have been obvious at the time of the invention to combine the teachings discussed above to arrive at the claimed invention.

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22. Claims 22-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Collins (US 2002/0006432 A1) in view of Van Der Mei (J. Med. Microbiol. 49:713-718). Claim 22 recites a method of treating and/or preventing the side-effects associated with the administration of nonsteroidal anti-inflammatory drugs, which method comprises administering to the patient an effective amount of a microorganism and/or a metabolite thereof, which microorganism and/or metabolite thereof at least increases the amount of a COX-1 mRNA in at least one cell of the subject. Claims 23 and 24 recite the method according to claim 22, wherein the microorganism and/or the metabolite thereof modifies the amount of a thither cyclooxygenase mRNA in said cell and wherein the microorganism and/or the metabolite thereof increases the amount of a COX-1 mRNA in said cell, whilst simultaneously decreases the amount of a COX-2 mRNA in said cell. Claims 25-27 recite the method according to claim 22, wherein the microorganism is a bacterium, specifically from the genus *Bifidobacterium*, specifically *Bifidobacterium* sp. 420.

23. Collins teaches a method of treating a subject by administering bacteria of the genus *Bifidobacterium* to a subject (abstract). The reference teaches that the bacteria may be administered in conjunction with NSAIDs (p. 4, par. 76). The functions recited in the claims, i.e., the effect on mRNA, would be inherent to the method of Collins. The reference does not specifically teach the use of *Bifidobacterium* sp. 420 in the method of using the bacteria.

24. Van Der Mei teaches the use of various strains of bacteria, including *Bifidobacterium* sp. 420, in methods for assessing their probiotic effects (abstract).

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25. At the time of the invention a method of administering the bacterium recited in the claims was known, as taught by Collins. It was further known that *Bifidobacterium* sp. 420 was an available species of bacteria, as taught by Van Der Mei, and further that the species may have probiotic effects. One of ordinary skill in the art would have been motivated to use *Bifidobacterium* sp. 420 in the method of Collins because Collins teaches that any species of *Bifidobacterium* with probiotic effects may be used in the method, and further teaches methods for testing such strains for probiotic effects (p. 2, par. 14-15, p. 4, par. 81-83). One would therefore have recognized that *Bifidobacterium* sp. 420 could have been tested for such effects and used in the methods of Collins. One of ordinary skill in the art would have had a reasonable expectation of success in using the strain in the methods of Collins because Collins teaches the use of using multiple *Bifidobacterium* strains in the methods. It would therefore have been obvious at the time of the invention to combine the teachings discussed above to arrive at the claimed invention.

26. Thus, the claimed invention as a whole was *prima facie* obvious over the combined teachings of the prior art.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHERIDAN R. MACAULEY whose telephone number is

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(571)270-3056. The examiner can normally be reached on Mon-Thurs, 7:30AM-5:00PM EST, alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SRM

/Ruth A. Davis/

Primary Examiner, Art Unit 1651